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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,538	10/31/2005	Yongzhi Xi	272331US0PCT	7166

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
10/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,538	XI ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges Claim amendments and Applicant's Remarks filed on 7/31/2007.

Claim Status

Claims 1-11 are canceled. Claims 12-21 are newly submitted. Claims 12-21 are under current examination.

Priority

This application claims benefit as a 371 of PCT/CN03/00967 (filed 11/14/2003). This application claims benefit from foreign patent application (CHINA) 02149375.8 (filed 11/14/2002). The instant application has been granted the benefit date, 14 November 2003, from the application PCT/CN03/00967.

Response to Arguments - Claim Objections

The cancellation of claims 5-6, filed 31 July 2007, have made the claim objections moot. Therefore, the examiner hereby withdraws the objections to claims 5-6.

Response to Arguments - Claim Rejections 35 USC § 112

Response to Arguments – 35 USC 112, second paragraph

Rejection of claims 1-3, 6-7 and 9-11 have been made moot by the claim amendments submitted on 31 July 2007 and are hereby withdrawn.

Response to Arguments – Written Description (35 USC 112, first paragraph)

Rejection of claims 1-5 have been made moot by the claim amendments submitted on 31 July 2007 and are hereby withdrawn.

Response to Arguments – ENABLEMENT (35 USC 112, first paragraph)

Rejection of claims 7-8 and 11 have been made moot by the claim amendments submitted on 31 July 2007 and are hereby withdrawn.

Response to Arguments - Claim Rejections 35 USC § 101

Rejection of claim 7 has been made moot by the claim amendments submitted on 31 July 2007 and are hereby withdrawn.

Response to Arguments - Claim Rejections 35 USC § 102

Rejection of claims 1-10 have been made moot by the claim amendments submitted on 31 July 2007 and are hereby withdrawn.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is directed to an isolated polynucleotide coding for the "protein of SEQ ID NO:2". According to the SEQLIST, SEQ ID NO:2 is not a protein, but a nucleic acid. The current claim language contains a logical inconsistency and clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

WRITTEN DESCRIPTION

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement;* (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claim 20 is broadly drawn, such that it applies to a genus of polypeptides having 95% homology to SEQ ID NO:3. However, specification contains no working examples polypeptides having 95% homology to SEQ ID NO:3. Furthermore, the specification does not describe which portions of SEQ ID NO:3 are structurally important and should be retained among the proteins that share 95% homology. MPEP § 2163, states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, ***even when accompanied by a method of obtaining the claimed sequence."***

The Revised Interim Guideline for Examination of Patent Applications under 35 USC § 112, p1 "Written Description" Requirement (Federal Register/ Vol 66. No 4, Friday January 5, 2001) states "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE

ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (column 2, page 71436, emphasis added).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION OF THE INVENTION. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, *WHATEVER IS NOW CLAIMED.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize the [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Considering the potentially large numbers of polypeptides encompassed by these claims, the disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.

NEW MATTER

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

The claimed invention is directed to an isolated polypeptide 95% homologous to SEQ ID NO:3." The specification indicates, "The CCII in the text of the presnet [sic] invention comprises the CCII of SEQ ID No.2, i.e., mature polypeptide, the polypeptide having at least 90% similarity to the polypeptide of SEQ ID No.2, 90% identity is preferable), and more preferable, having ate [sic] least 95% similarity, and 95% identity is preferable. It also includes part of said polypeptide containing at least 30 amino acids, preferably having more than at least 50 amino acids." (page 13, parag.2). The specification does indicate whether the phrases "identity", "homologous", and "similarity" have the same meaning. In addition, there is some confusion, perhaps a typographical error in the specification on page 13, where the applicant refers to SEQ ID NO:2 as a polypeptide. As described in the 35 USC 112, 2nd rejection, SEQ ID NO:2 is not a polypeptide, but a polynucleotide. While the specification indicates that a polypeptide having 95% is preferable, the specification also indicates that the chicken collagen II polypeptide encompassed by the invention has at least 90% similarity...at least 95% similarity...95% identity is preferable (page 13, parag.2). It is not clear that the claim language of claim 20, wherein the isolated polypeptide is exactly 95% homologous to

SEQ ID NO:3. The examiner believes there is no support for this claim language, therefore it is new matter.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 20 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Xi et al. (accession number AAK98621, direct submission on 19 July 2001).

Claim 20 is directed to an isolated polypeptide 95% homologous to SEQ ID NO:3. The sequence submitted by Xi et al. in 2001 is 100% identical to SEQ ID NO:3.

Therefore, accession number AAK98621 anticipates or is obvious over the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) in view of Matsumoto et al (US-6,010,722, issued 4 January 2000).

Claim 12 is directed to an isolated polynucleotide of SEQ ID NO:1. The specification describes SEQ ID NO:1 as genomic DNA encoding chicken collagen II (page 26 and 10). Upholt et al. teach genomic DNA chicken α1 (II) procollagen gene.

Claim 13 is directed to an isolated polynucleotide of SEQ ID NO:2. The specification describes SEQ ID NO:2 as chicken collagen II cDNA. Upholt et al.

describe sequencing of the mRNA encoding regions of chicken collagen α1 (II) (page 2325). Inherently, the cDNA sequence is known.

Claims 14-19 are directed to vectors and cells comprising the chicken collagen II genes of claims 12-13, recombinant proteins generated therefrom, method of producing recombinant chicken collagen II, compositions of recombinant chicken collagen II, food additives comprising recombinant chicken collagen II.

Matsumoto et al. teach, "oral drugs and functional foods [which] contain type-II collagen" (abstract). Matsumoto et al. teach that the type II collagen can be chicken collagen (col.3, line 40). Matsumoto et al. teach that the type-II collagen can be made using "recombinant DNA technology" (col.3, lines 46-47). Intrinsically, to use recombinant DNA technology for producing type-II chicken collagen, a skilled artisan would need to have cells comprising vectors comprising isolated nucleic acids encoding chicken collagen II. To the extent to which the pharmaceutical composition comprising CCII might have an enabled use (e.g. – a food additive), Matsumoto et al. teach the limitations of claims 14-19.

The applicant asserts that the chicken collagen II taught by Matsumoto et al is not the same as that taught by the instant application. However, the chicken collagen II genes taught by Upholt et al. are without a doubt the same as those claimed by the instant application.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to utilize the sequences of Upholt et al. to express recombinant

forms of chicken collagen II for use in the pharmaceutical compositions of Matsumoto et al.

Regarding the rationale for simple substitution of one known, equivalent element for another to obtain predictable results, the claim(s) would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Each of the elements (specific chicken collagen II sequences and methods of recombinant protein production of chicken collagen II and uses therefor) is taught by Upholt et al. or Matsumoto et al. It would be therefore predictably obvious to substitute a known element (chicken collagen II nucleic acid) in recombinant production of chicken collagen II for food additives.

Therefore the products and methods as taught by Upholt et al. in view of Matsumoto et al. would have been *prima facie* obvious over the products and methods of the instant application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JLE